REMARKS

Reconsideration of the subject patent application is respectfully requested.

The Examiner has raised a number of issues under 35 U.S.C. § 112 and considering the claim cancellations and amending changes to the remaining claims, Applicants believe that all of the 35 U.S.C. § 112 issues have been properly addressed and resolved. Clearly, if any further 35 U.S.C. § 112 issues remain, Applicants will endeavor to make further changes, as deemed necessary. However, the current Response is believed to be responsive in total to all of the issues raised by the Examiner.

Claims 37-63 are presently pending in this application and claims 46-49 and 56-60 have been withdrawn from consideration. This leaves claims 37-45, 50-55, and 61-63. These claims have been rejected by the Examiner based on one or more prior art references. In order to try and address all of the issues raised by the Examiner, claims 37-49 have been canceled and claims 56-60 have been canceled. This leaves claims 50-55 and 61-63 as pending in this application. These claims have been amended in an effort to address the concerns raised by the Examiner and to more clearly focus on differences between the claimed composition and treatments and what is disclosed by the cited prior art references.

As reflected by the claim cancellations and amendments, the treatments associated with the claimed nanocompound have been limited to neoplastic and cancerous disorders of the human or animal body in order to overcome the respective objections raised by the Examiner, stating that the genus or wording "*disorders*" would be too vague and too broad.

Further, by the amendments to the claims, Applicants have addressed the respective objections raised by the Examiner with respect to the breadth of the claims, the absence of working examples, and the quantity of experimentation necessary. The claims have been limited to those compounds, for which full experimental data is provided already in the original application. In the inventive Examples, those compounds were synthesized and subsequently tested with respect to their toxicity and also their effectiveness in view of various cancer cells. Surprisingly, these specific compounds show an excellent effectiveness with respect to various cancerous cells of different origin, which could not be expected by one of ordinary skill in the art.

Further, the nanocompounds themselves and their physiologically tolerated salts are only claimed. Derivatives, isomers, hydrates, metabolites and/or products thereof have been excluded or deleted, respectively, in order to overcome the respective objections raised by the Examiner.

The types of compounds which are used according to the claims are known, which is also acknowledged by the Applicants (see pages 21/22 of the translated specification), describing in detail the chemical synthesis of these kinds of compounds with reference to the specific literature. However, part of what is new and also inventive is the fact that, as discovered by Applicants, these specific compounds show an excellent effectiveness in the treatment of cancer cells.

None of the prior art references cited by the Examiner disclose the use of the specifically selected compounds in the treatment of neoplastic and cancerous disorders of the human or animal body, nor does a combination of these references render the claimed subject matter obvious.

U.S. Patent No. 5,360,895 (*Hainfeld et al.*).

This reference refers to derivatized gold clusters and antibody-gold cluster conjugates containing 6, 8, 9, 11, 13, 55 or 67 gold atoms in their inner core and which are intended for electron microscopy applications as well as for limited clinical applications including imaging, diagnosis and therapy.

The specific compounds which Applicants disclose and claim are not disclosed at all in this reference. The effectiveness and tolerability of therapeutics may not be extrapolated. These properties strongly depend on the whole compound consisting of core and ligand structure. Therefore, the *Hainfeld et al.* reference does not allow any extrapolation with respect to the inventive compounds being different from those disclosed in the *Hainfeld et al.* reference. In whole pharmaceuticals, such extrapolation of structure/effectiveness is not possible at all.

This reference was cited by the Examiner only due to the original breadth of the original claims. Considering the claim cancellations and amendments, this reference has limited relevance and may no longer be considered pertinent.

Further, it was not foreseeable to a person of ordinary skill in the art that gold cluster nanocompounds of the specific structure as claimed would possess these

extraordinary properties in the treatment of cancerous disorders. Even if the *Hainfeld et al.* reference discloses gold clusters, this does not allow any extrapolation for other gold clusters, such as the specific gold clusters claimed due to the aforementioned unforeseeable relationship of core and ligand in the same way.

***Sponer et al.* reference (J. Phys. Chem. Vol. 103, 1999, pp. 11406-11413).**

This reference was only cited due to the original breadth of the claims since this reference discusses metal-stabilized rare tautomers and mispairs of DNA bases. This reference discusses, on a very theoretical level, the molecular electrostatic potential of adenine and mercurated adenine. This, however, does not have anything in common with the present invention, the latter referring to the use of very specific Au_{55} nanoclusters with the specific ligand chemistry for the treatment of neoplastic and cancerous diseases.

***Peschel et al.* reference (Angewandte Chemie, Int. Ed., Vol. 34, No. 13/14, 1995).**

This reference describes monolayers of ligand-stabilized gold clusters. *Inter alia*, the gold clusters generally disclosed and claimed by Applicants are described with respect to their monolayer structure when applied to a poly(ethyleneimine) carrier, i.e. a mica plate coated with poly(ethyleneimine). However, this reference does not have anything in common with the current claims since no medical application for these kinds of compounds is envisaged there.

As stated before, Applicants explicitly acknowledge that the compounds of the type recited in the claims are known. However, what is new and inventive over the prior

art is the fact that Applicants have discovered that these compounds are useful therapeutic agents in the treatment of neoplastic and cancerous diseases.

The assessment by the U.S. Examiner that the claims are obvious over a combination of the *Hainfeld et al.* reference over *Peschel et al.* is based on a mere hindsight view. The *Hainfeld et al.* reference teaches compounds of a completely different chemical structure. Therefore, as stated before, this reference does not allow for any extrapolation of any other gold clusters since there does not exist any foreseeable relationship between a therapeutic compound comprising a core and a ligand chemistry, on the one hand, and its therapeutic effectiveness, on the other hand. Such data can only be brought about on an empirical level by running the respective experiments. Any other assessment would be based on hindsight knowledge, which is not appropriate as a basis to formulate a rejection.

On the whole, the present invention is now clearly delimited over the prior art citations since none of the prior art documents anticipates nor even suggests a combination of the inventive features according to the amended independent claims. The specific compound and treatments which are claimed are neither realized nor rendered obvious in view of the aforementioned references. Thus, the present claims are not only novel over the cited prior art, but are also inventive because the claimed compound and treatments were not obvious to the person of ordinary skill in the art.

Considering the claim cancellations, claim amendments and further explanations, claims 50-55 and 61-63 are considered to be in condition for allowance.

Respectfully submitted,

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